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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,664	06/26/2003	Takatomo Hisamatsu	018961-063	3993
7590	11/27/2006			EXAMINER POUS, NATALIE R
BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404				ART UNIT 3731 PAPER NUMBER

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/603,664	HISAMATSU ET AL.
	Examiner Natalie Pous	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 August 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-23,25 and 26 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-23,25 and 26 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                       |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/30/05, 12/30/04, 6/28/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application             |
|  | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

**DETAILED ACTION**

***Response to Arguments***

**Regarding the Abstract**

Examiner acknowledges submission of amended abstract to conform to the 150 word requirement. The objection to the abstract is withdrawn

**Regarding Berg**

Applicant's arguments, see response, filed 8/4/06, with respect to Berg have been fully considered and are persuasive. The 35 USC 102 rejections with respect to Berg have been withdrawn.

**Regarding Keith**

Applicant's arguments, see response, filed 8/4/06, with respect to the rejection(s) of claim(s) 1 and 12 under Keith have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Wijeratne et al. (US 6036670)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 3, 5, 6, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al. (US 6036670) in view of Berg et al. (US 5911715). Wijeratne teaches a catheter comprising the following: a proximal shaft (32); a distal shaft (22) connected to a front portion of said proximal shaft; a hub (34) provided to the rear side of said proximal shaft; a balloon (21) provided at a front portion of said distal shaft; a balloon lumen for communicating said hub to the inside of said balloon; and a guide wire lumen (23) for allowing a guide wire to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (25) positioned on the distal side from a front end of said balloon and a proximal side aperture (26) positioned on the rear side from a rear end of said balloon;

Wijeratne fails to teach the following:

- wherein at least a front portion, positioned on the rear side from said balloon, of said distal shaft is configured as a grooved portion having a groove.
- wherein said groove is formed into spiral shape or annular shape.

- wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter.
- wherein the depth of said groove is in a range of 30 to 90% of the wall thickness of said distal shaft.
- wherein the depth of said groove is changed in the direction toward the distal end of said catheter.
- wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in said second region is larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region.
- wherein said grooved portion is provided at a portion adjacent to said balloon.
- wherein said groove is formed in an outer surface of said distal shaft.

Berg teaches a guide catheter capable of carrying a balloon wherein, at least a front portion, of said distal shaft (56) is configured as a grooved portion having a groove (61), wherein said groove is formed into spiral shape or annular shape (fig. 10), wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein the depth of said groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in

said second region is larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region (fig. 11c) and wherein said groove is formed in an outer surface of said distal shaft (fig. 9) in order to provide a device having increased flexibility for better maneuverability. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Wijeratne with the grooved portion as taught by Berg in order to provide a device having increased flexibility for better maneuverability.

Claims 1, 2, 7, 8, 10-14, 16-20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith (US 5217482) in view of Berg (US 5911715).

Keith teaches a catheter comprising the following:

- a proximal shaft (22); a distal shaft (66) connected to a front portion of said proximal shaft (22); a hub (42) provided to the rear side of said proximal shaft; a balloon (26) provided at a front portion of said distal shaft (fig. 1); balloon lumen (106) for communicating said hub (Column 5, proximate lines 55-58) to the inside of said balloon; and a guide wire lumen (52) for allowing a guide wire (50) to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (94) positioned on the distal side from a front end of said balloon (26) and a proximal side aperture (92) positioned on the rear side from a rear end of said balloon (26);
- a proximal shaft (22) having a high rigidity (Column 6, proximate liens 60-65), a distal shaft (66) provided on a front portion of said proximal shaft so as to be in

fluid communication with said proximal shaft (Fig. 2) and having a rigidity lower than that of said proximal shaft (Column 8, proximate lines 36-40); a hub (42) connected to the vicinity of a rear end of said proximal shaft (22) and configured to allow a pressure applying apparatus to be connected to said hub (Column 5, proximate lines 55-58); a balloon (56) provided on a front side of said distal shaft so as to be in fluid communication with said distal shaft and a guide wire lumen (52) for allowing a guide wire to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (94) positioned on the front side from a front end of said balloon and a proximal side aperture positioned on the rear side (92) from a rear end of said balloon;

- wherein said distal shaft is made from a polymer material having a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cm<sup>2</sup> or more (Column 7, proximate lines 34-36). Keith teaches wherein the distal shaft is formed of a high-density polyethylene, which inherently has a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cm<sup>2</sup>.
- wherein said distal shaft has a distal portion (34) and a proximal portion (110), and the rigidity of said proximal portion (110) of said distal shaft is lower than that of said proximal shaft (22) and is higher than that of said distal portion (34) of said distal shaft (Column 9, proximate lines 1-10).

Keith fails to teach the following:

- wherein at least a front portion, positioned on the rear side from said balloon, of said distal shaft is configured as a grooved portion having a groove.
- A catheter according to claim 12, wherein said groove is formed into spiral shape or annular shape.
- A catheter according to claim 12, wherein said grooved portion is provided at a portion adjacent to said balloon.
- wherein said groove is formed in an outer surface of said distal shaft.
- wherein said grooved portion is positioned on the rear side from said balloon
- wherein the pitch of said spiral or annular groove is changes over the length of the grooved portion of the distal catheter

Berg teaches a guide catheter capable of carrying a balloon wherein, at least a front portion, of said distal shaft (56) is configured as a grooved portion having a groove (61), wherein said groove is formed into spiral shape or annular shape (fig. 10), wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein the depth of said groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in said second region is larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region (fig. 11c) and wherein said groove is formed in an outer surface of said distal shaft (fig.

9) in order to provide a device having increased flexibility for better maneuverability. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Keith with the grooved portion as taught by Berg in order to provide a device having increased flexibility for better maneuverability.

Regarding the limitation wherein the pitch of said spiral or annular groove is changes over the length of the grooved portion of the distal catheter, Berg teaches a catheter wherein the grooved portion may have varying width and depths in order to provide variation in flexibility from groove to groove. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Keith with varying pitch of the spiral groove in order to provide variation in flexibility along the grooved portion.

Claims 4, 9, 15, 21, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Keith and Berg as applied to claims 1 and 12 above, and further as a matter of design choice.

The combination of Keith and Berg teaches all of the limitations of preceding dependent claims 1 and 12 as previously disclosed, but fails to describe the following:

- wherein the depth of said groove is in a range of 30 to 90% of the wall thickness of said distal shaft.
- wherein the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more.

Regarding the limitations wherein the groove is in a range of 30 to 90% of the wall thickness of said distal shaft and the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more, the combination of Keith and Berg teaches a device wherein the grooves are in place in order to provide a smooth transition from the proximal rigid portion to the more flexible distal portion (Berg), but does not teach the exact depth of the grooves in relation the thickness of the shaft. It appears that the combination of Keith and Berg performs the task of providing a smooth transition from the proximal rigid portion to the more flexible distal portion equally well as that disclosed in the application. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose make the depth of the groove in a range of 30 to 90% of the wall thickness of the distal shaft and the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP  
10/10/06

  
**ANHTUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

*10/15/06*

Continuation of Attachment(s) 6). Other: IDS: 12/10/03, 11/12/03, 6/26/03.